EXHIBIT B



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February 16, 2022

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Re: In re Valsartan, Losartan, and Irbesartan Products Liability Litigation USDC, District of New Jersey, No. 1:19-md-2875-RBK-KMW

Dear Counsel:

I write on behalf of the Defendants' Executive Committee to request the production of documents in the possession, custody, and control of Dr. Ron Najafi and his business, Emery Pharma. Dr. Najafi at deposition confirmed his laboratory performed testing for nitrosamines on valsartan drug product manufacturered by Defendants to this litigation, some of which was obtained from named Plaintiffs. Further, Dr. Najafi indicated Emery performed confirmatory testing of valsartan product in conjunction with Valisure's citizen petition submitted to FDA on June 13, 2019, which showed the presence of NDMA in Novartis's reference listed drug (RLD).

These data and related documents and communications are plainly relevant to class certification. First, the information bears on the two core assumptions underpinning Dr. Najafi's opinions—namely, that (i) all of the Defendants' valsartan contained NDMA and/or NDEA, and (ii) none of Novartis's RLD contained NDMA and/or NDEA. Even more broadly, testing demonstrating the presence or absence of nitrosamine impurities in the Defendants' valsartan goes to central questions at issue at the Rule 23 stage, particularly in light of Plaintiffs' theory regarding "Lifetime Cumulative Thresholds" and the value of Defendants' medication.

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Accordingly, Defendants request the production of the following materials within ten (10) days:

- 1. The results of all testing performed by Emery Pharma and/or Valisure on any valsartan drug substance or drug product;
- 2. The standard operating procedures, protocols, methods (including validation) governing any such testing:
- 3. All reports and data generated related to any such testing;
- 4. The standard operating procedures, protocols, and policies related to the sourcing and chain of custody for all samples of valsartan drug substance or drug product received by Emery, including materials identifying the patient to whom the medication was prescribed, manufacturer, NDC, and batch/lot number;
- 5. All correspondence to, from, and among representatives of Emery Pharma and/or Valisure regarding any testing performed on valsartan or the citizen petition submitted to FDA on June 13, 2019; and
- 6. All invoices generated by Dr. Najafi and/or Emery Pharma related to this testing.

Otherwise, we intend to raise this issue with the Court.

Respectfully submitted,

Clem C. Trischler

Plaintiffs' Executive Committee (valpec@kirtlandpackard.com) c: Defendants' Executive Committee (DEC@btlaw.com)